

### **REMARKS**

In the office action, the claims have been objected to, and rejected under 35 USC §§ 101, 112, 102 and 103. In response, Applicants have amended claims 14-17, 20, and 22, added new claim 23, cancelled claims 18, 19 and 21, and provide the herein remarks. Accordingly, claims 14-17, 20 and 22-23 are pending in the application. Reconsideration is respectfully requested.

A request for continued examination is being filed herewith.

### **Claim Objections**

The claims have been objected to on several grounds. Claims 16, 17, 20 and 22 have been objected to due to syntax.

Claims 16, 17 and 20 have been amended to recite “wherein the method comprises administering...” as suggested by the Examiner. Claim 22 has been amended to recite “autologous IL-15, wherein said method comprises administering to a host...” as the Examiner has suggested. Applicants thank the Examiner for the suggested improvements to the syntax of the claims.

Claim 15 has been objected to as being improper for allegedly failing to further limit the subject matter of claim 14.

In response, Applicants have amended claim 14 to recite *native* IL-15 as an antigen to emphasize that the IL-15 used as an antigen has the same amino acid sequence as autologous IL-15. Claim 14, as amended, now recites that the composition also contains aluminum hydroxide. Claim 15 has been amended to be an independent claim,

and to clearly recite that the IL-15 claimed is NOT *native*. Rather, the IL-15 of claim 15 is recombinant IL-15, and thus, has a glycosylation pattern that is different from *native* IL-15.

Accordingly, Applicants submit that the above objections have been rendered moot.

### **Rejections Under §101**

In the office action, claims 19 and 21 have been rejected under 35 USC §101 as being directed to non-statutory subject matter. In particular, the Examiner contends that the claims lack required steps.

In response, Applicants have amended claims 19 and 21 to read “administered” instead of “used.” Accordingly, Applicants respectfully submit that the rejection under §101 has been rendered moot.

### **Rejections Under §112, First Paragraph**

Claims 16-22 have been rejected under 35 USC §112, first paragraph, as allegedly lacking enablement for methods of treating an “IL-15 expression-related disorder.” The Examiner contends that the claims are excessively broad because they read on treating “any IL-15 expression related disease.”

In response, Applicants have amended the claims to refer to specific diseases. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Claims 19 and 21 have been rejected under 112, first paragraph, as lacking enablement in as far as concurrent use of an anti-inflammatory drug or cytokine antagonist. In response, Applicants have cancelled claims 19 and 21. Accordingly, the rejection has been rendered moot.

**Rejections Under §112, Second Paragraph**

Claims 19 and 21 have been rejected under §112, second paragraph as being indefinite. In response, Applicants have cancelled the claims. Accordingly, Applicants respectfully request that the above rejection under §112, second paragraph, has been rendered moot.

**Rejections Under §102**

Claim 14 has been rejected under §102(b) as being anticipated by U.S. Patent No. 6,013,480 to Grabstein et al. (hereinafter "Grabstein I"). According to the Examiner, Examiner 2 of Grabstein I. disclose a vaccine composition comprised of yeast derived human IL-15 that stimulates production of anti-human IL-15 antibody producing cells in mice. The Examiner recognizes that Grabstein I do not specifically recite a composition comprised of IL-15 that generates self-antibodies to autologous IL-15. However, the Examiner asserts that it would be expected to do so, in the absence of evidence to the contrary.

In response, Applicants have amended claim 14 to more clearly define the invention. Amended claim 14 recites a composition comprising native IL-15 as an antigen, and aluminum hydroxide, for generating neutralizing self-antibodies against autologous IL-15. Support for this amendment can be found, e.g., in the specification on page 1, line 11.

Grabstein I does not disclose compositions comprising native IL-15 as an antigen, and aluminum hydroxide. Therefore, Grabstein I does not anticipate the claims. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §102(b) rejection based on Grabstein I.

Claims 14, 16 and 22 have been rejected under §102(a) as being anticipated by U.S. Patent No. 6,344,192 to Grooten et al. According to the Examiner, Grooten et al. disclose a pharmaceutical composition comprised of human IL-15.

As mentioned above, Applicants have amended claim 14 to more clearly define the invention. Amended claim 14 recites a composition comprising native IL-15 as an antigen, and aluminum hydroxide, for generating neutralizing self-antibodies against autologous IL-15.

Grooten et al. do not disclose using a composition comprising native IL-15, and aluminum hydroxide. Accordingly, claims 14, 16 and 22 are not anticipated by Grooten

et al. Applicants respectfully request that the Examiner reconsider and withdraw the §102 rejection based on Grooten et al.

Claims 14-16 and 22 have been rejected under §102(b) as being anticipated by Grabstein et al. (WO 95/27722) (hereinafter "Grabstein II"). According to the Examiner, Grabstein II discloses isolation and cloning of human IL-15, that IL-15 can be recombinantly produced in *E.coli*, and pharmaceutical compositions comprising recombinant IL-15 produced in *E.coli*.

As mentioned above, Applicants have amended claim 14 to more clearly define the invention. Amended claim 14 recites a composition comprising native IL-15 as an antigen, and aluminum hydroxide, for generating neutralizing self-antibodies against autologous IL-15.

Grabstein II do not disclose using a composition comprising native IL-15, and aluminum hydroxide. Accordingly, claims 14, 16 and 22 are not anticipated by Grabstein II. Applicants respectfully request that the Examiner reconsider and withdraw the §102 rejection based on Grabstein II.

### **Rejections Under §103**

Claims 14-22 have been rejected under §103 as being unpatentable over a combination of Grabstein I and Gonzalez et al.(Scand. J. Immunol. 2000, Vol. 52, p. 113-116), and further in view of Grabstein II.

According to the Examiner, Grabstein I and II disclose compositions comprising IL-15, including recombinant IL-15 produced in *E. coli*. The Examiner also contends that Gonzalez discloses coupling a carrier protein to a polypeptide in order to increase the immunogenicity of the polypeptide.

As mentioned above, Applicants have amended claim 14 to more clearly define the invention. Amended claim 14 recites a composition comprising native IL-15 as an antigen, and aluminum hydroxide, for generating neutralizing self-antibodies against autologous IL-15.

In order to establish a prima facie case of obviousness, the cited documents, when combined, must disclose or suggest all of the claimed elements. Applicants have demonstrated the importance of the composition comprising both IL-15 and aluminum hydroxide.

Upon combining Grabstein I and II, and Gonzalez, et al., the claimed invention is not disclosed or suggested. Therefore, the claimed invention is patentable over Grabstein I and II, and Gonzalez et al.

Accordingly, Applicants respectfully request that the §103 rejection based on Grabstein I and II, and Gonzalez et al. be reconsidered and withdrawn.

Applicants believe the application is now in condition for allowance. Should the Examiner feel that a telephone discussion with Applicants representative would be helpful in resolving any issues, he is invited to contact the undersigned at his convenience.

Respectfully submitted,



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